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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,589	03/29/2004	Eric Tomasetti	TR-6132 (BXTC 4021)	2100
7590	10/12/2006			
Mr. Joseph B. Barrett Baxter Healthcare Corporation One Baxter Parkway, DF3-2W Deerfield, IL 60015				EXAMINER MC CLELLAND, KIMBERLY KEIL
			ART UNIT 1734	PAPER NUMBER

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/811,589	TOMASETTI ET AL.
	Examiner	Art Unit
	Kimberly K. McClelland	1734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 July 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-23 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-8,16, and 17 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S. Patent Application Publication No. 2003/0143352 A1 to Yang et al.

With respect to claim 1, Yang et al. discloses a method for connecting flexible tubing wherein the tubing is placed in an axial end-to-end position (See Figures 2A and 2B), using a laser directed to heat the tube ends (paragraph 0068), and bringing them into contact with each other (paragraph 0071).

As to claim 2, Yang et al. is silent as to the temperature of the tubing ends before the laser is activated. However, in order for the tubing to be in a solid state prior to the welding process, the temperature of the tubing ends must be below the melting temperature of the material forming the tubing section. Yang et al. discloses that the laser melts the tubing (paragraph 0069).

As to claim 3, Yang et al. discloses the use of a material (film) to absorb energy from the laser at the tube ends (paragraph 0072).

As to claim 4, Yang et al. discloses a sheet of material (film), which has a high concentration of dye to absorb energy of the laser (paragraph 0072).

As to claim 5, Yang et al. discloses that the tubing material is substantially transparent (not laser responsive) to the electromagnetic beam (paragraph 0127).

As to claim 6, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071) and flow outward when heated (paragraph 0072).

As to claim 7, Yang et al discloses that dye may be applied to the tube ends (areas to be joined) that are welded by the laser (paragraph 0129).

As to claim 8, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071).

As to claim 16, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071), and flow outward (paragraph 0072).

As to claim 17, Yang et al. discloses that a laser is directed at the tube ends (paragraph 0068).

3. Claims 18-20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,345,070 to Hlavinka et al.

4. With respect to claim 18, Hlavinka et al. discloses a radio frequency tubing sealer, including collapsing at least a portion of the tubing section (See Figures 2-3); placing the collapsed portion of the tubing section in contact with an energy absorption member (12); directing a beam of electromagnetic energy onto the energy absorption member (column 5, lines 11-13), the energy absorption member being constructed for absorbing energy from the beam (column 4, lines 18-26); and transferring heat from the

energy absorption member to the collapsed tubing section portion by contact therewith to melt and seal the collapsed tubing section portion in its collapsed configuration (column 5, lines 25-35).

5. As to claim 19, Hlavinka et al. discloses the energy absorption member has low thermal conductivity (column 4, lines 15-18).

6. As to claim 20, Hlavinka et al. discloses the energy absorption member comprises a block (column 5, lines 36-41; See Figure 5).

7. As to claim 22, Hlavinka et al. discloses the energy absorption member is a film (column 4, lines 41-46).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0143352 A1 to Yang et al. as applied to claims 1-8, 16, and 17 above, and further in view of U.S. Patent No. 5,674,333 to Spencer.

Yang et al. discloses a method for connecting two pieces of tubing as disclosed above. Yang et al. also discloses that all the welding method is carried out in the axial position (See Figures 4A-4F). However, Yang does not disclose cutting off end portions of the tubing sections.

As to claim 9, Spencer discloses an apparatus for welding together two sections of tubing, including a method of cutting of end sections of tubing prior to welding (column 3, lines 14-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a method of cutting the tubing sections prior to welding, as taught by Spencer, with the laser welding method of Yang et al. in the axial position in order to ensure proper connection during welding.

10. Claims 10-15 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. and Spencer as applied to claim 9 above, and further in view of U.S. Patent No 4,832,773 to Shapaska et al.

Yang et al. and Spencer disclose a method of welding tubing sections together. Spencer also teaches the method of squeezing the tubing sections to reopen the passage (column 3, lines 38-40). However, Yang et al. and Spencer do not disclose the clamping of the tubing.

As to claim 10, Shapaska et al. discloses a method for connecting sections of tubing, including clamping the cut (pre-cut) tubing sections (column 3, lines 48-51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a method of clamping the tubing sections, as taught by Shapaska et al., with the laser welding method of Yang et al. and Spencer to keep the tubing sections stationary.

As to claim 11, Yang et al. discloses sealing the tube ends prior to welding the tubing sections together (paragraph 0072).

As to claim 12, Yang et al. discloses the use of a weld block (drum head) to absorb energy from the laser and combine with the tube (paragraph 0072).

As to claim 13, Spencer teaches the method of squeezing the tubing sections to reopen the passage (column 3, lines 38-40).

As to claim 14, Spencer teaches the movement of welded tubing (weld sample) from one location (device) to a remote location (vise column 3, line 62- column 4, line 12).

As to claim 15, Yang et al. discloses that all the welding method is carried out in the axial position (See Figures 4A-4F).

As to claim 23, Yang et al. discloses the step of providing material for absorbing energy comprises positioning a sheet of material between the axial surfaces of the of the tubing sections (See Yang et al. paragraph 0066), wherein the sheets are capable absorbing the energy of the electromagnetic beam (See Yang et al. paragraph 0072).

11. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,345,070 to Hlavinka et al. as applied to claims 18-20 and 22 above, and further in view of U.S. Patent Application Publication No. 2003/0226631 to Sterud et al.

Hlavinka et al. discloses an electromagnetic sealing method as taught above. Hlavinka also discloses the energy absorption member is an insulating material and more preferably polypropylene (column 4, lines 26-40). However, Hlavinka et al. do not teach the use of glass or polytetrafluoroethylene energy absorption members.

As to claim 21, Sterud discloses a welding method, including using weld blocks (sleeve) of glass or polytetrafluoroethylene (See Paragraph 0086). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the glass or polytetrafluoroethylene taught by Sterud et al. with the sleeve of the tubing sealing method of Hlavinka et al. to use a more rigid material, and ease movement of the tubing in the sleeve (See paragraph 0086).

Response to Arguments

12. Applicant's arguments, see brief, filed 7/21/06, with respect to the rejection(s) of claim(s) 18-22 under Yang in view of various secondary references have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art.

13. With respect to applicant's argument against the rejection of claims 1 under 35 U.S.C. 102(e) over Yang, examiner disagrees. Firstly, the phrase "end-to-end" does not require direct intimate contact. The addition of the phrase "free from exposure to the surrounding environment" must be interpreted broadly. Consequently, in the method of Yang, prior to activation of the welding device, the tubing sections are placed in opposed end-to-end relationship and have sealed ends which are free from exposure to the surrounding environment meet the limitations as set forth in the current claim. Furthermore, there is nothing in the claim language to suggest the laser may only be operated once. As a result, any melting done before the tubing is placed in direct

intimate contact is insignificant. Moreover, applicant only claims the tubing is free from exposure when placed end-to-end. There is no claim language that suggests the tubing sections must remain sterile during the entire welding process.

14. Applicant also argues the Yang references only allows for welding during the first activation of the laser, and is incapable of welding the tubing sections during the second laser activation step. Examiner disagrees. During the second operation of the laser, energy is used to heat and sterilize the tubing connection. The same laser is being used twice on the same section of tubing. Therefore, if welding occurs during the first activation of the laser, the subsequent activation inherently welds the tubing sections.

15. As to applicant's argument the Yang reference teaches the tubing ends are melted when they initially contact eachother, examiner agrees. However, applicant does not claim tubing sections are not melted when initially brought into contact.

16. With respect to applicant's arguments directed towards dependent claim 2, examiner disagrees. Firstly, in the Yang reference, the tubing sections are initially placed end-to-end prior to any activation of the laser welder. Once again, it is emphasized by the examiner that "free from exposure to the surrounding environment" does not require direct intimate contact. The tubing sections are assumed to be at room temperature, and therefore, below the melting temperature of tubing material. In addition, after initial welding of the tubing sections, it is assumed the weld seam solidifies and the temperature of the tubing sections returns to room temperature. Consequently, prior to the second activation of the laser welder, the tubing sections are below the melting temperature of the tubing material as well.

17. Regarding applicant's arguments towards dependent claims 6 and 16, examiner disagrees. Firstly, the phrase "brought together" appears nowhere in either claim. In addition, examiner asserts that during the welding step of Yang, wherein the tubing sections are moved toward eachother, some pressure from the movement causes compression forces in the tubing ends. The resulting forces, along with the heat energy from the laser cause the tubing section to flow outwardly.

18. Thus, the rejection of claims 1-17 and 23 over Yang and various secondary references is maintained. New rejections have been issued for claims 18-22. It is believed that all outstanding arguments have been addressed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly K. McClelland whose telephone number is (571) 272-2372. The examiner can normally be reached on 8:00 a.m.-5 p.m. Mon-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris A. Fiorilla can be reached on (571)272-1187. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KKM

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